REMARKS

The final Office Action mailed July 21, 2009 has been carefully reviewed and this paper is responsive thereto. Claims 1-37 are pending. Claims 1-37 stand rejected.

Claim Rejections Under 35 USC §102 and §103

Claims 1-6, 12-13, 17, 20, 22-31 and 33-36 are rejected under 35 USC §102(e) as being anticipated by or, in the alternative, under 35 USC §103(a) as obvious over Mann, U.S. Publication No. 2001/0034542 ("Mann"). Applicants respectfully traverse this rejection.

Claim 1

The rejection of claim 1 disregards the written specification as originally filed and the language of dependent claim 4, which differentiates what is "tolerable to the patient" from "a range of safety." For example, the specification as originally filed states (at page 55, paragraph [170] (which corresponds to the paragraph [0182] of the application published as US 2004/0138516)):

> In step 2705, a beginning of a detection cluster is recognized in accordance with the seizure detection algorithm 800. Detection of a seizure will trigger delivery of a treatment therapy (in this case stimulation), which may be redelivered during a detection cluster (e.g., cluster duration 2205) until the seizure has been terminated or **safety limits** (such as maximum stimulation on time per given period of time) **have been reached or tolerability becomes an issue**. [Emphasis added].

In accordance with the specification, a "range of safety" as claimed in independent claim 1 is different than what is tolerable to a patient. Claim 4 states:

> [t]he method of claim 1, further comprising:
>
> (f) receiving an indication from the user whether the first treatment therapy is tolerable to the patient; and
>
> (g) if the first treatment therapy is not tolerable, executing a corresponding action.

Claim 4 shows that what may be tolerable to the patient is indeed different from "a range of safety" as claimed in independent claim 1. Claim 1 is directed toward a method that includes the step of "assessing whether the first set of information is within a range of safety." (emphasis added). The final Office Action suggests that Mann disclosed this, pointing to page 2, paragraph 12 of Mann, in particular, "a clinician using such neural stimulation system may immediately jump between two or more electrode sets, each of which has the stimulation magnitude levels automatically adjusted to, e.g., a minimum perception threshold level, a maximum tolerable threshold level, or a selected value between the minimum perception and maximum tolerable threshold levels." (Mann, pg. 2, para. [0012]) (emphasis added). The final Office Action states that Mann thus discloses a range between the minimum perception threshold level and the maximum tolerable threshold level, which the Applicants agree with.

However, the final Office Action goes on to state that "since the stimulation is in a range of the minimum perception threshold level, a maximum threshold level, or a selected value between the minimum perception and maximum tolerable threshold levels, the examiner considers the stimulation to be within a range of safety." (Office Action, pg. 2) (emphasis added). The Applicants respectfully disagree with this generalization of the range of safety. The Applicants respectfully submit that it is incorrect to equate perceptibility and tolerability with safety, as the final Office Action has done in the above statement. In other words, the final Office Action suggests that even though the term safety is not mentioned in Mann and there is no discussion in Mann of assessing whether information is within a range of safety, the disclosure of Mann inherently discloses the concept of safety. The Applicants are unaware of any support for the proposition in the final Office Action that the range between a minimum perception level and a maximum tolerable level is the same as a range of safety. The Office Action has provided no support for such a proposition and logically the two are not the same. Applicants submit that many types of treatments might be within the range disclosed in Mann, over the minimum perception level and under the maximum tolerable level, but would be considered unsafe.

Additionally, the proposition that perceptibility or tolerability equates to safety does not address the feature recited in claim 1, "assessing whether the first set of information is within a range of safety." For example, as discussed on page 35-37 of the specification as filed, charge

density is based on the shape and configuration of the electrode as well as the stimulation applied. This concept is distinct from the concept of perceptibility and tolerability or the determination of a magnitude of voltage or current that may be delivered (as is discussed in paragraph 12 of Mann). *See also*, the specification as originally filed at page 55, paragraph [170] (which corresponds to the paragraph [0182] of the application published as US 2004/0138516), which differentiates between safety limits and tolerability, and dependent claim 4, which separately claims a feature relating to tolerability that is distinct from the feature of "assessing whether the first set of information is within a range of safety," as claimed in independent claim 1. Thus, a tolerable stimulation for the patient in a first electrode might be safe while a similar stimulation in a second electrode (which might still be tolerable because it was the same magnitude) might be unsafe. Consequently, a stimulation level that the patient would perceive within a tolerable range might be unsafe, depending on how it was applied. Thus, an assessment that a treatment is perceived or tolerable does not address the issue of whether the treatment is safe. In particular, the specification as filed explains on page 37, paragraph 119 that "[i]n other embodiments, a treatment therapy level that is beyond the point at which the user stops delivery is considered as not tolerated by the patient" and states separately that "the medical device system may insure that the treatment therapy configuration corresponds to a treatment that is safe to the patient, where the treatment therapy configuration is within a configuration range of safety." In accordance with the specification, "safety to the patient is gauged by an expectation that the treatment does not diminish the health of the patient" and it is not possible to determine whether a "perceived" or "tolerable" treatment will or will not diminish the health of the patient.

Furthermore, as noted on page 35 of the specification as filed, treatment parameters could include a number of variables such as stimulation time, pulse shape, etc. Therefore, additional safety issues such as charge balancing (see specification as filed, pg. 36-37), and the like could arise, making what was otherwise a "tolerable" treatment unsafe.

The basis for the Office Action's rejection of the claims is that a range between the minimum tolerable level and a maximum tolerable level equates to a range of safety. However, for at least the reasons discussed above, Applicants respectfully submit that it is incorrect to equate treatment that is perceived and tolerable with treatment that is safe. Therefore, the Office

Action has failed to provide support that Mann discloses an assessment of whether information is within a range of safety.

Furthermore, Claim 1 recites the feature "if the first treatment therapy is safe, storing the first set of information for subsequent use." The Examiner failed to point to any disclosure in Mann as disclosing this feature. The prior Office Actions have failed to point to any location in Mann as disclosing this feature. Thus, to date there has been no support provided for the suggestion that Mann discloses this feature of claim 1. Consequently, the Examiner has not met the burden of providing a basis for the rejection of claim 1 based on Mann for this additional reason.

Therefore, for at least the above reasons, Mann fails to disclose all the features of claim 1. As Mann fails to disclose all the features of claim 1, claim 1 is patentable in view of Mann.

Claims 2-6, 12, 13, 17, 20, 22-24, and 34-36

Claims 2-6, 12, 13, 17, 20, 22-24, and 34-36 depend from claim 1. Therefore, claims 2-6, 12, 13, 17, 20, 22-24, and 34-36 are patentable for at least the reasons that claim 1 is patentable and for the additional features recited below. Applicants respectfully request withdrawal of the rejection of claims 2-6, 12, 13, 17, 20, 22-24, and 34-36.

Claims 25-31

Independent claim 25 recites features similar to the features discussed above with respect to claim 1. Therefore, claim 25 is patentable in view of Mann for reasons similar to the reasons discussed above with respect to claim 1. Claim 26, which depends from claim 25, highlights that what may be tolerable to the patient is different from "a range of safety" as claimed in independent claim 25.

Additionally, the Applicants submit that the Examiner has not pointed to any location in Mann that discloses an apparatus as claimed in claim 25. In other words, even if the Examiner had properly shown support for the rejection of claim 1, which was not done, the suggestion that Mann discloses an apparatus with the features recited in claim 25 is not supported. In particular, the Examiner has only pointed to a clinician as allegedly performing certain steps recited in claim 25. Thus, even if the Examiner's position was supported, which it is not, Mann would still

fail to disclose the features recited in Claim 25. Thus, for this additional reason, claim 25 is patently distinct in view of Mann.

Claims 26-31 depend from claim 25 and are patentable for at least the reasons that claim 25 is patentable and for the additional features recited therein. Therefore, Applicants respectfully request withdrawal of the rejection of claims 25-31.

Claims 7-11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann or the modified Mann as to claims 1-6, 12-13, 17, 20, 22-31 and 33-36 above. Applicants respectfully traverse this rejection.

Claims 7-11

Claims 7-11 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable and for the additional features recited therein. In addition, claims 7-11 have an additional basis for being patentable.

The Office Action admits that Mann fails to disclose the feature of claims 7-11 but suggests that claims 7-11 are obvious in view of Mann anyway because, while Mann fails to disclose the recited features, there is allegedly no disclosure regarding the advantages of such an approach. As previously submitted, however, the features of claim 7-11 are not merely design choices and advantages have been provided for the recited features. Thus, the rationale used by the Examiner in rejecting claims 7-11 is not supported and is inconsistent with the support provided for why the claimed features are patentably distinct.

First, no support has been provided for the suggestion that the features of claim 7 are design choices. Claim 7 recites the feature of "receiving the first label from the user" and further recites the feature of "applying a subsequent treatment therapy in accordance with the first label." The Examiner suggested these features were design choices. However, the Applicants respectfully submit that this suggestion is without support. The Examiner has provided no support for the proposition that such a feature is normally considered a design choice (such as has been held for cases where claims merely recite a minor shape change). In addition, potential advantages of the claims were previously provided. For example, one potential advantage of receiving labels from the user, as recited in claim 7, is that it can help simplify the selection of treatment options, which would otherwise be so numerous as to make selection difficult. The

Examiner failed to address this issue and in view of the lack of any other support (legal or factual) for the rejection, it cannot properly be maintained.

Second, no support has been provided for the suggestion that the features of claims 8-11 are design choices. Claim 8 recites the feature of "receiving another set of information from the user, the other set of information being associated with another treatment therapy configuration" and further recites the feature of "associating another label with the other set of information" and further recites the feature of "comparing the first set of information and the other set of information." The Examiner suggested these features were design choices. However, the Examiner has provided no support for why such features can be considered merely a design choice. The claim features, for example, are not simple shape changes or a simple separation into two parts what was known to be a single part. Indeed, the Examiner has failed to show these feature were even known in the art. Furthermore, Applicants have expressly provided a basis for why these features are not merely design choices. For example, one potential advantage of the recited features of claim 8 is the ability to compare different treatment therapy configurations before saving them. Given the limited memory for storing information and the potential confusion of having two treatments that are essentially the same, such a step allows for subsequent steps such as saving the information or providing a notification to the user, depending on whether the information is essentially unique. The Examiner's apparent overlooking of this information appears to be the only reasons for why the rejection was maintained because once the information is considered, the purported rationale of the rejection fails – instead it becomes clear that the recited features are not obvious design choices.

Claims 9-11 depend from claim 8 and therefore also recite features that cause them to be patentably distinct in view of Mann for at least the above reasons and for the additional features recited therein. For example, claim 9 recites the feature of "if the other treatment therapy configuration is essentially unique, storing the other set of information and the other label" and the Examiner has failed to put forth a logical basis for why such a step would be considered an obvious design choice. In addition, claim 10 recites the feature of "if the other treatment therapy configuration is not essentially unique, outputting a notification to the user" and the Examiner has failed to put forth a logical basis for why such a step would be considered an obvious design choice.

Therefore, for at least the above reasons, claims 7-11 are patentable in view of Mann. Applicants respectfully request withdrawal of the rejection of claims 7-11.

Claim 21

Claim 21 depends from claim 1 and is patentable for at least the reasons that claim 1 is patentable and for the additional features recited therein. Therefore, Applicants respectfully request withdrawal of the rejection of claim 21.

Claims 14-16 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann or the modified Mann as to claims 1-6, 12-13, 17, 20, 22-31 and 33-36 above, in view of Whitehurst, et al., U.S. Patent Application 2004/0015205 ("Whitehurst"). Applicants respectfully traverse these rejections.

Claims 14-16 and 32

Claims 14-16 and 32 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable and for the additional features recited therein. In addition, claims 14-16 and 32 have an additional basis for being patentable.

Claim 14 recites the feature of "determining a surface area of the electrode" and further recites the feature of "determining a charge density that is associated with the electrode." The Examiner admitted that Mann fails to disclose this feature but suggested that Whitehurst corrected the deficiency. In particular, the Office Action suggested that disclosure of the use of a relatively large electrode surface somehow disclosed the claim feature. Whitehurst merely discloses, however, the use of large electrodes "also requires electrodes with a relatively large surface area, so as to maintain safe levels of charge density and current density." (Whitehurst, pg. 3, para. [0046]). In particular, the Examiner has failed to point to any portion of Whitehurst as disclosing "determining a surface area of the electrode" or as disclosing "determining a charge density that is associated with the electrode."

Applicants respectfully assert that merely suggesting that a large surface area is beneficial falls short of disclosing the recited features. In other words, the mere suggestion that larger currents require more surface area falls far short of disclosing the step of "determining a surface

area of the electrode" recited in claim 14. For example, Whitehurst does not disclose any type of determining with respect to surface area of electrodes. The cited portion of Whitehurst also completely fails to disclose determining a charge density. Thus, the Office Action has failed to provide any support for these features being present in the references of record.

Claims 15-16, which depend from claim 14, also recite additional features related to the determining of charge density and current and the cited references make no mention of such steps. Claim 32 recites features similar to the above discussed features of claim 14. Accordingly, for at least the reasons discussed above, the references of record fail to disclose all the recited features and the rejection fails to present a prima facie case of obviousness. Therefore, Applicants respectfully request withdrawal of the rejection of claims 14-16 and 32.

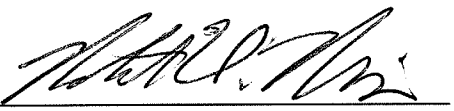
Claim 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann or the modified Mann as to claims 1-6, 12-13, 17, 20, 22-31 and 33-36 above, in view of Esteller, et al., U.S. Patent No. 6,594,524 ("Esteller"). Applicants respectfully traverse these rejections.

Claims 18 and 19 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable and for the additional features recited therein. Therefore, Applicants respectfully request withdrawal of the rejection of claims 18 and 19.

Conclusion

Applicants respectfully requests reconsideration of the pending claims and a finding of their allowability. A notice to this effect is respectfully requested. Please feel free to contact the undersigned should any questions arise with respect to this case that may be addressed by telephone.

Date: September 21, 2009

By: 

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